

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

---

**IN RE: JOHNSON & JOHNSON  
TALCUM POWDER PRODUCTS  
MARKETING, SALES  
PRACTICES, AND PRODUCTS  
LIABILITY LITIGATION**

---

**Civil Action No. 3:16-md-2738-  
FLW-LHG  
MDL No. 2738**

***THIS DOCUMENT RELATES TO ALL CASES***

---

**THE PLAINTIFFS' STEERING COMMITTEE'S REPLY TO  
DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON  
CONSUMER INC.'S MEMORANDUM OF LAW IN OPPOSITION TO  
PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE  
OPINIONS OF DEFENDANTS' EXPERTS BROOKE T. MOSSMAN, M.S.,  
PH.D., KELLY S. TUTTLE, PH.D., AND H. NADIA MOORE, PH.D.**

---

## TABLE OF CONTENTS

|   |    |
|---|----|
| TABLE OF CONTENTS .....   | 2  |
| TABLE OF AUTHORITIES .....  | 4  |
| I. INTRODUCTION .....   | 6  |
| II. ARGUMENT .....  | 7  |
| A. THE EXPERT OPINIONS OF DR. BROOKE T. MOSSMAN SHOULD BE EXCLUDED BECAUSE SHE IS UNQUALIFIED TO RENDER THEM, AND THEY ARE BASED ON AN UNSOUND METHODOLOGY.....   | 7  |
| 1. Dr. Mossman “Cherry-Picked” The Studies And Materials She Relied On, Contrary To A Methodologically Sound And Reliable Approach For Evaluating A Scientific Question.....  | 7  |
| a. Dr. Mossman’s inadequate review of the epidemiological literature.   | 8  |
| b. Dr. Mossman’s inadequate review of the biological literature .....   | 10 |
| c. Dr. Mossman’s inadequate review of the data on migration.....  | 12 |
| 2. Dr. Mossman Is Inadequately Qualified To Opine On Many Of The Topics For Which She Offers An Expert Opinion, Particularly Relating To Her Opinions About Mineralogy, Cellular And Molecular Responses, And Migration Processes ..... | 13 |
| 3. Dr. Mossman’s Critiques of the PSC’s Experts Drs. Saed and Zelikoff Are Without Merit.....   | 14 |
| B. THE EXPERT OPINIONS OF KELLY S. TUTTLE, PH.D. SHOULD BE EXCLUDED BECAUSE SHE LACKS THE REQUISITE EXPERIENCE AND EMPLOYED UNRELIABLE METHODS IN REACHING HER OPINIONS AND IN CRITICIZING THE OPINIONS OF THE PSC’S EXPERTS .....      | 15 |
| 1. Dr. Tuttle’s Attempt To Minimize The Toxicity Of Talcum Powder Products By Unreliably Limiting Her Analysis Is Scientifically Unsound  | 16 |
| 2. Dr. Tuttle Lacks The Requisite Experience To Criticize The PSC’s Experts.....  | 18 |
| 3. Dr. Tuttle’s Opinion On Migration Is Unsupported And Unreliable ....   | 22 |
| 4. Dr. Tuttle’s Opinions On Inflammation And Carcinogenicity Lack Substance And Are Unreliable.....   | 26 |

|   |    |
|---|----|
| C. THE EXPERT OPINIONS OF NADIA H. MOORE SHOULD BE EXCLUDED BECAUSE SHE LACKS ANY EXPERIENCE IN CANCER AND CELL BIOLOGY RESEARCH QUALIFYING HER TO CRITICIZE THE PSC’S EXPERTS AND BECAUSE THE METHODOLOGY SHE EMPLOYED IN REACHING HER OPINIONS ARE UNRELIABLE.... | 28 |
| 1. Dr. Moore Lacks The Necessary Experience And Training To Criticize Dr. Saed’s Cancer And Cell Biology Research .....   | 28 |
| 2. Dr. Moore’s Opinions On The Mineralogy And Presence Of Particulates In Talcum Powder Products And Related Opinions On Talcum Powder Products Testing Should Be Excluded.....   | 30 |
| 3. Dr. Moore’s Cherry-Picked Opinion On Causal Association Should Be Excluded.....  | 31 |
| III.CONCLUSION.....   | 34 |

## **TABLE OF AUTHORITIES**

### **Cases**

|   |           |
|---|-----------|
| <i>Daubert v. Merrell Dow Pharm., Inc.</i> ,<br>509 U.S. 573 (1993).....                                    | 6, 19, 22 |
| <i>Elcock v. Kmart Corp.</i> ,<br>233 F. 3d 734 (3d Cir. 2000) .....  | 9         |
| <i>In re Fosamax Prod. Liab. Litig.</i> ,<br>645 F. Supp. 2d 164 (S.D.N.Y 2009) .....                       | 12        |
| <i>In re: Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.</i> ,<br>858 F.3d 787 (3d Cir. 2017) ..... | 10        |
| <i>Magistrini v. One Hour Martinizing Dry Cleaning</i> ,<br>180 F. Supp.2d 584 (D.N.J. 2002).....           | 9         |
| <i>Milward v. Acuity Special Prods. Group</i> ,<br>639 F.3d 11 (1st Cir. 2011).....                         | 10        |

### **Other Authorities**

|   |        |
|---|--------|
| A.J. Ghio, J.M. Soukup, L.A. Dailey, J.H. Richards, J.L. Turi, E.N. Pavlisko, V.L. Roggli, Disruption of iron homeostasis in mesothelial cells after talc pleurodesis, <i>Am J Respir Cell Mol Biol</i> 46(1) (2012) 80-86 .....          | 32     |
| Blumenkrantz et al., “Retrograde Menstruation in Women Undergoing Chronic Peritoneal Dialysis,” <i>Obstetrics &amp; Gynecology</i> 57(5): 667-670, at p. 669 (1981) .....   | 13     |
| Egli and Newton, “The Transport of Carbon Particles in the Human Female Reproductive Tract,” <i>Fert. &amp; Ster.</i> 12: 151-155, at p. 153 (1961).....  | 13     |
| Health Canada, Draft Screening Assessment, Talc (December 2018) .....   | 31, 32 |
| J.C. Wagner, G. Berry, T.J. Cooke, R.J. Hill, F.D. Pooley, J.W. Skidmore, Animal experiments with talc, in: W.H. Walton, B. McGovern (Eds.), <i>Inhaled Particles IV</i> , Part 2, Pergamon Press, 714 Oxford, UK, 1977, pp. 647–654..... | 32     |
| L.-m. Chen, J.S. Berek, Epithelial carcinoma of the ovary, fallopian tube, and peritoneum: Epidemiology and risk factors, <i>UpToDate</i> , 2014 .....  | 32     |

|   |    |
|---|----|
| Lo-Ciganic, W. H., J. C. Zgibor, C. H. Bunker, K. B. Moysich, R. P. Edwards and R. B. Ness (2012). Aspirin, nonaspirin nonsteroidal anti-inflammatory drugs, or acetaminophen and risk of ovarian cancer. <i>Epidemiology</i> 23(2): 311-319..... | 32 |
| M.M. van den Heuvel, H.J. Smit, S.B. Barbierato, C.E. Havenith, R.H. Beelen, P.E. Postmus, Talc-induced inflammation in the pleural cavity, <i>Eur Respir.J</i> 12(6) (1998) 1419-1423 .....  | 32 |
| N. Nasreen, D.L. Hartman, K.A. Mohammed, V.B. Antony, Talc-induced expression of C-C and C-X-C chemokines and intercellular adhesion molecule-1 in mesothelial cells, <i>Am J Respir Crit Care Med</i> 158(3) (1998) 971-8 .....                  | 32 |
| Narod S (2016). Talc and ovarian cancer. <i>Gynecologic Oncology</i> 141(3):410-12.   | 32 |
| Ness, R. B. and C. Cottreau (1999). Possible role of ovarian epithelial inflammation in ovarian cancer. <i>Journal of the National Cancer Institute</i> 91(17): 1459-1467 .....   | 32 |
| Rohl A, A. Langer, J. Selikoff, A. Tordini, R. Klimentidis (1976). Consumer talcums and powders: mineral and chemical characterization. <i>Journal of Toxicology and Environmental Health</i> 2(2):255-84 .....                                   | 33 |
| Shukla, et al., <i>Alterations in gene expression in human mesothelial cells correlate with mineral pathogenicity</i> , <i>Am J Respir Cell Mol Biol</i> , 2009;41:114-123.11, 31, 32, 33   |    |
| Sjosten et al., “Retrograde migration of glove powder in the human female genital tract,” <i>Human Reprod.</i> 19: 991-995, at p. 995 (2004) .....  | 13 |
| Venter and Iturralde, “Migration of a Particulate Radioactive Tracer from the Vagina to the Peritoneal Cavity and Ovaries,” <i>S. Afr. Medi. J.</i> 55: 917-919, at pp. 918, 919 (1979).....  | 13 |

## **Rules**

|                             |   |
|-----------------------------|---|
| Fed. R. Evid. 104 (a) ..... | 6 |
| Fed. R. Evid. 403 .....     | 6 |
| Fed. R. Evid. 702 .....     | 6 |
| Fed. R. Evid. 703 .....     | 6 |

## **I. INTRODUCTION**

The Plaintiffs' Steering Committee ("PSC") submits this reply in further support of its motion<sup>1</sup> to exclude certain toxicology expert witnesses and in reply to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s ("J&J") opposition to the PSC's Toxicology Motion.<sup>2</sup> The opinions of these experts do not comport with the requisite standards for the admissibility of expert opinions pursuant to Fed. R. Evid. 104 (a), 403, 702, and 703 and *Daubert*. The reliability of the experts' opinions is scientifically suspect, their methodologies are flawed, and the experts lack the requisite foundational support and experience to satisfy *Daubert*.

J&J's arguments in support of the admissibility of these experts' opinions rests on misleading accounts of their reports, testimony and opinions. When these misleading accounts are exposed, it is clear that the opinions of these experts fall short of the requirements of *Daubert* and should be excluded.

---

<sup>1</sup> See *Plaintiffs' Steering Committee's Motion to Exclude the Opinions of Defendants' Toxicology Experts Brooke T. Mossman, M.S., PH.D., Kelly S. Tuttle, PH.D., and H. Nadia Moore, PH.D.*, (ECF No. 9739-1). ("PSC's Toxicology Motion").

<sup>2</sup> See *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Opposition to Plaintiffs' Steering Committee's Motion to Exclude the Opinions of Defendants' Experts Brooke T. Mossman, M.S., PH.D., Kelly S. Tuttle, PH.D., and H. Nadia Moore, PH.D.*, (ECF No. 9874). ("J&J's Opposition to PSC's Toxicology Motion").

## II. **ARGUMENT**

### A. **THE EXPERT OPINIONS OF DR. BROOKE T. MOSSMAN SHOULD BE EXCLUDED BECAUSE SHE IS UNQUALIFIED TO RENDER THEM, AND THEY ARE BASED ON AN UNSOUND METHODOLOGY**

As the Court is well aware, the issue pending before the Court is whether genital use of Talcum Powder Products can cause ovarian cancer. Dr. Mossman, an expert in pathology and laboratory medicine, was retained by J&J to answer that question. The methodology Dr. Mossman employed to answer this question is unreliable.

#### 1. **Dr. Mossman “Cherry-Picked” The Studies And Materials She Relied On, Contrary To A Methodologically Sound And Reliable Approach For Evaluating A Scientific Question**

Dr. Mossman failed to systematically review, analyze, and consider the totality of the scientific data presented on the use of Talcum Powder Products.<sup>3</sup> The literature and science on Talcum Powder Products, and more specifically, on biological plausibility including migration of Talcum Powder Products, is evidenced

---

<sup>3</sup> The PSC discusses the law relating to the impropriety of an expert “cherry-picking” information in the *Plaintiffs’ Steering Committee’s Reply to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Response to the Plaintiffs’ Steering Committee’s Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation* (“PSC’s Omnibus Reply Brief”), filed concurrently herewith, and incorporated herein by reference.

in countless epidemiological, pathological, biological and mechanistic studies conducted and published in the peer-reviewed literature over the last four decades.

Dr. Mossman did not conduct a proper and thorough review of the literature or available scientific evidence to reach her opinions. Instead, she elected to: 1) review selected and limited epidemiological and biological studies without an analysis and reconciliation of their strengths and weaknesses; 2) apply and employ improper methodology to her analysis of the data;<sup>4</sup> and 3) focus on isolating the carcinogenic constituents of Talcum Powder Products to argue that the biologic effects, toxicity and carcinogenic properties of Talcum Powder Products and cleavage fragments are different from asbestos.<sup>5</sup>

Notably, Dr. Mossman did not review or consider internal company documents, including J&J and Imerys test results of its Talcum Powder Products conducted over decades, nor the test results of Drs. Longo and Rigler. Instead, she assumed for purposes of her opinions that Talcum Powder Products did not contain asbestos.<sup>6</sup>

**a. Dr. Mossman's inadequate review of the  
epidemiological literature**

---

<sup>4</sup> See PSC's Toxicology Motion at 17.

<sup>5</sup> See J&J's Opposition to PSC's Toxicology Motion, at 3.

<sup>6</sup> See PSC's Toxicology Motion at 20, *citing to*, Mossman Deposition at 179:21-180:8; 199:22-200:3.



Dr. Mossman's review of the literature was materially incomplete. She reviewed only a portion of the epidemiological studies on Talcum Powder Products and ovarian cancer in reaching her opinion that there was insufficient evidence to support a causal association between the two. Dr. Mossman admitted having reviewed a limited, certain group of epidemiological studies and did not consider all the relevant epidemiological and mechanistic studies. The Third Circuit deems expert opinions unreliable where the expert ignores material evidence when formulating his or her opinions.<sup>7</sup> To this end, while she specifically testified that she looked at cohort studies and a subgroup of 14 to 20 case-control studies demonstrating an "increased risk" of ovarian cancer, she did not review all of these studies and as to those that she did review, she gave little weight because she believed these studies lacked "statistical significance."<sup>8</sup> To be clear, statistical significance is not required, and a district court should not "read too much" into the

---

<sup>7</sup> See *Elcock v. Kmart Corp.*, 233 F. 3d 734, 756 (3d Cir. 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp.2d 584, 602 (D.N.J. 2002) ("in order for an expert's opinions based on evidence to be reliable and admissible, all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.").

<sup>8</sup> Mossman Dep. at 149:17-151:5. *Compare with* PSC'S Toxicology Motion at 14 (discussing the existence over more than thirty observational studies on the association between Talcum Powder Products and ovarian cancer).

issue of the lack of “statistical significance” of an individual study.<sup>9</sup> Dr. Mossman did not weigh the totality of the evidence. The epidemiological studies related to genital use of talcum powder and ovarian cancer show consistent odds ratios greater than 1.0, with most in the range of 1.2-1.6.<sup>10</sup> The results of the majority of these studies are statistically significant. Rather than consider the evidence in its totality, Dr. Mossman chose to cherry-pick evidence favorable to her opinion and reject other evidence based on a lack of statistical significance.<sup>11</sup>

**b. Dr. Mossman’s inadequate review of the biological literature**

Dr. Mossman’s review of the biological and mechanistic literature is similarly insufficient to meet the requirements for performing a sound methodological inquiry. When asked what methodology she employed in formulating her opinions about whether talcum powder could cause ovarian cancer she testified:

I have read the literature in terms of the lack of migration of talc to the ovary. I’ve read the epidemiology. And I do have an opinion that is

---

<sup>9</sup> See *Milward v. Acuity Special Prods. Group*, 639 F.3d 11, 24 (1st Cir. 2011) (holding that “[t]he court erred in treating the lack of statistical significance as a crucial flaw’); *In re: Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 793 (3d Cir. 2017) (declining to state a bright-line rule on whether statistical significance is necessary noting that “a standard based on replication of statistically significant finding obscures the essential issue: a causal connection.”)

<sup>10</sup> PSC’s Omnibus Reply Brief at [REDACTED].

<sup>11</sup> Mossman Dep. at 149:17-151:5.

based upon the peer-reviewed scientific medical literature that talc is not associated with the causation of ovarian cancers.<sup>12</sup>

Dr. Mossman's opinions are nothing more than *ipse dixit*— unsupported assertions that fail to consider many of the relevant peer-reviewed studies on Talcum Powder Products and ovarian cancer. In performing her analysis in this manner, she has largely ignored the numerous studies that focus on the role of migration and inflammation<sup>13</sup> and “cherry picks” evidence relevant to the talcum powder/ovarian cancer questions. Most concerning is that she ignored published data from her own studies which conflict with her opinions rendered in this litigation.<sup>14</sup> J&J seems to think that because Dr. Mossman reviewed one post-2006 study, the 2009 Keskin rat study, that any serious deficiencies in her review have been cured. But reviewing one more recent study is not sufficient.

What is important is that the totality of the data needs to be considered, and not just limited data that is favorable to one's position. Taken as a whole, the failure of Dr. Mossman to describe her methodology, to demonstrate that she adequately

---

<sup>12</sup> Mossman Dep. at 129:22-130:5.

<sup>13</sup> See *Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Plaintiffs' Expert' Opinions Related to Biological Plausibility*, (ECF No. 9890) (“PSC's Opposition to J&J's Biologic Plausibility Motion”) at 10-31.

<sup>14</sup> Shukla (2009) (findings support the proposition that Talcum Powder Products cause an inflammatory response); see also PSC's Toxicology Motion at 21-23.

reviewed and considered a panoply of relevant literature and weighed the evidence pertaining to biological plausibility, renders the reliability of her opinions suspect. Dr. Mossman's opinions and material omissions lack prerequisite scientific foundation and should be excluded.

**c. Dr. Mossman's inadequate review of the data on migration**

Dr. Mossman opines that there is no "proof" that Talcum Powder Products migrates to the ovaries. From the outset she applies the wrong standard for biological plausibility. There is no requirement that the precise mechanism by which migration and ovarian carcinogenesis be proven.<sup>15</sup> She stakes out this position despite her admission that she has not studied the topic.<sup>16</sup> Thus, in addition to applying the wrong standard on biological plausibility she fails to consider the totality of evidence in forming her opinions, rendering them unreliable. In her expert report she concludes that "it is difficult to conceive of a route whereby talc" after perineal dusting would reach the ovaries and persist in sufficient doses to cause ovarian cancer. This common rejoinder is made once again in the absence of consideration of a large body of relevant literature demonstrating a biologic mechanism whereby "particulates" of the same size can ascend the female

---

<sup>15</sup> See *In re Fosamax Prod. Liab. Litig.* 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009).

<sup>16</sup> See PSC's Toxicology Motion at 24 (*citing* Mossman Dep. at 210:24-211:5).

reproductive tract.<sup>17</sup> Her characterization of the migration theory as “unproven” demonstrates once again her misapplication of the standard for biologic plausibility – proof is not required in science or law.<sup>18</sup>

**2. Dr. Mossman Is Inadequately Qualified To Opine On Many Of The Topics For Which She Offers An Expert Opinion, Particularly Relating To Her Opinions About Mineralogy, Cellular And Molecular Responses, And Migration Processes**

Dr. Mossman admits to a lack of appropriate experience and to certain limitations that render her unqualified. While the PSC acknowledges that Dr. Mossman is a toxicologist with experience in asbestos-related lung diseases, she concedes that she is not an epidemiologist, mineralogist, geologist or materials analyst *and would defer to a mineralogist for particle analysis*.<sup>19</sup> She also conceded that she has never studied generally cosmetic-grade talc or more specifically Talcum Powder Products’ cellular and molecular responses and migration processes.<sup>20</sup>

---

<sup>17</sup> See PSC’s Toxicology Motion at 24-25. For example, Dr. Mossman failed to consider numerous studies that support migration of particulates to the upper genital tract: Sjosten et al., “Retrograde migration of glove powder in the human female genital tract,” *Human Reprod.* 19: 991-995, at p. 995 (2004); Blumenkrantz et al., “Retrograde Menstruation in Women Undergoing Chronic Peritoneal Dialysis,” *Obstetrics & Gynecology* 57(5): 667-670, at p. 669 (1981); Venter and Iturralde, “Migration of a Particulate Radioactive Tracer from the Vagina to the Peritoneal Cavity and Ovaries,” *S. Afr. Med. J.* 55: 917-919, at pp. 918, 919 (1979); Egli and Newton, “The Transport of Carbon Particles in the Human Female Reproductive Tract,” *Fert. & Ster.* 12: 151-155, at p. 153 (1961).

<sup>18</sup> See PSC’s Opposition to J&J’s Biologic Plausibility Motion at n. 2, 3.

<sup>19</sup> PSC’s Toxicology Motion at 4; Mossman Dep. at 18:23-19:6 & 21:2-17.

<sup>20</sup> PSC’s Toxicology Motion at 5; Mossman Dep. at 67:9-17.

These admitted limitations, when coupled with Dr. Mossman's testimony and written opinions which reveal that she engaged in only a selected review of the literature and that she made an arbitrary analysis of the data (including her own), makes her opinions subject to strong methodologic challenges.<sup>21</sup> Beyond this, she redefined biological plausibility<sup>22</sup> and lacks the understanding or appreciation that Talcum Powder Products are mixtures of numerous constituents, including asbestos, platy talc, fibrous talc, heavy metals and fragrances, several of which are human carcinogens.<sup>23</sup>

Dr. Mossman's uninformed, biased and myopic review of the science and data along with an incorrect redefining of biological plausibility forms the basis of her opinion that Talcum Powder Products do not cause ovarian cancer. These opinions simply cannot be defended.

### **3. Dr. Mossman's Critiques of the PSC's Experts Drs. Saed and Zelikoff Are Without Merit**

---

<sup>21</sup> See PSC's Toxicology Motion at 14-17.

<sup>22</sup> Compare Mossman Dep. at 349:12-350:22 (suggesting plausibility be proven) with PSC's Opposition to J&J's Biologic Plausibility Motion at 1, 8, 9 (discussing biologic plausibility as not requiring proof and citing Hill and corresponding Third Circuit precedent in support thereof).

<sup>23</sup> See *Plaintiffs' Steering Committee's Omnibus Memorandum of Law in Response and Opposition to Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower-to-Shower*, (ECF No. 9885) ("PSC's Opposition to J&J's Heavy Metals Motion") at 1.

Dr. Mossman levels unfounded criticism upon Drs. Saed and Zelikoff. The arguments in support of the admissibility of the opinions of these experts have been set forth extensively in the PSC's oppositions to J&J's motions to exclude these expert witnesses.<sup>24</sup> As to Dr. Saed, J&J and Dr. Mossman's allegations regarding his handling of the lab notebooks, the presentation of the study data, and the source of funding for his studies are unfounded, completely devoid of support in the record, and should be excluded.<sup>25</sup>

**B. THE EXPERT OPINIONS OF KELLY S. TUTTLE, PH.D. SHOULD BE EXCLUDED BECAUSE SHE LACKS THE REQUISITE EXPERIENCE AND EMPLOYED UNRELIABLE METHODS IN REACHING HER OPINIONS AND IN CRITICIZING THE OPINIONS OF THE PSC'S EXPERTS**

Dr. Tuttle is a toxicologist and industrial hygienist retained by J&J to render opinions regarding the association between genital use of Talcum Powder Products and ovarian cancer and to critique the opinions of the PSC's experts.<sup>26</sup> Dr. Tuttle's

---

<sup>24</sup> See generally PSC's Opposition to J&J's Biologic Plausibility Motion; PSC's Opposition to J&J's Heavy Metals Motion; and *Plaintiffs' Steering Committee's Omnibus Memorandum of Law in Response and Opposition to Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Plaintiffs' Experts' Opinions for Lack of Qualifications*, (ECF No. 9886).

<sup>25</sup> See, *The Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to Defendants' Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Expert Opinions Related of Ghassan Saed* (ECF No. 9875) ("PSC's Opposition to Exclude Saed"); see also May 23, 2019 Letter Opinion of Special Master Pisano, (ECF No. 9828).

<sup>26</sup> In her report, Dr. Tuttle states that her objective as an expert in the matter is: "to assess the scientific literature regarding the alleged causal relationship between

qualifications are not the central focus of the PSC's motion to exclude her opinions. Rather it is her lack of in-depth analysis and methodology employed in support of her opinions. Dr. Tuttle's repeated reliance on the opinions of other experts combined with her admitted failure to more carefully review or consider the totality of the available science leaves the trier of fact with only her *ipse dixit* opinions.

**1. Dr. Tuttle's Attempt To Minimize The Toxicity Of Talcum Powder Products By Unreliably Limiting Her Analysis Is Scientifically Unsound**

From the outset, Dr. Tuttle ignores the fact that Talcum Powder Products are "cosmetic products" which contain mixtures of numerous constituent parts including asbestos, platy talc, fibrous talc, heavy metals, and fragrance chemicals, all of which play a role in causing ovarian cancer. She omits from her analysis the fact that many of the constituents contained in Talcum Powder Products are established and widely recognized human carcinogens, including asbestos, fibrous talc, nickel, and chromium VI. These carcinogens contribute to the biologically plausible mechanism – inflammation – by which Talcum Powder Products can cause ovarian cancer.<sup>27</sup>

---

cosmetic talcum powder exposure and ovarian cancer, specifically with regard to the potential exposures to talc, asbestos, heavy metals and fragrant chemicals....[A]lso been asked to assess the scientific methodology used by certain of the plaintiffs' expert in their assessment of the scientific literature and their independent research and opinions in their causal assessments." Tuttle Report at 1.

<sup>27</sup> PSC's Opposition to J&J's Heavy Metals Motion at 1-2.



Dr. Tuttle improperly examined the association between ovarian cancer and certain heavy metals (chromium, nickel, cobalt, lead, cadmium and arsenic) and chemical fragrances that she chose to investigate, to the exclusion of other constituents contained in Talcum Powder Products. She did so by considering the association of each of these constituents in isolation, and not as they are combined in Talcum Powder Products.<sup>28</sup> In other words, to support her opinions, she limited her review of Talcum Powder Products and focused her analysis on six heavy metals and fragrance chemicals and their association with ovarian cancer.<sup>29</sup> Through this narrowed prism, she ignores the heterogeneous mixture of Talcum Powder Products with their carcinogenic and other toxic constituents. All of this is offered in an attempt to minimize the overall toxicity of Talcum Powder Products by discussing each individual constituent as if it is in its own silo.<sup>30</sup> The combination of these constituents results in a synergistic impact that Dr. Tuttle ignores by her compartmentalizing the constituents and assessing each individually and not as a combined end-product, Talcum Powder Products.

---

<sup>28</sup> J&J's Opposition to PSC's Toxicology Motion at 7.

<sup>29</sup> *Id.* at 7-8.

<sup>30</sup> Dr. Tuttle admits she failed to consider whether the heavy metals included in the Talcum Powder Products might be captured within the lattice or structure of the talc. Tuttle Dep. at 423:21-424:5.

In like manner, Dr. Tuttle's superficial analysis fails to address the roles of migration and transport as to the heavy metals and fragrance constituents of the Talcum Powder Products' "cocktail."<sup>31</sup> Focusing on extremely limited evidence or ignoring the totality of available and relevant scientific evidence renders an expert opinion unreliable and scientifically unsound.<sup>32</sup>

## **2. Dr. Tuttle Lacks The Requisite Experience To Criticize The PSC's Experts**

Throughout Dr. Tuttle's deposition, and as exhibited in her plagiarized expert report, Dr. Tuttle demonstrates a clear lack of working competency in her purported fields of expertise. Under even a liberal standard for admitting rebuttal expert testimony, these deficiencies should render her opinions criticizing the PSC's experts as inadmissible.

As discussed above, Dr. Tuttle failed to independently consider the totality of available and relevant scientific evidence and improperly attempts to minimize the toxicity of these dangerous products by compartmentalizing her review of their constituent elements. It is illogical, therefore, to think that Dr. Tuttle would have the

---

<sup>31</sup> Dr. Tuttle's report includes an Appendix related to JBP's 141 and STS's 53 fragrance chemical, yet only discusses nine (9) within the body of her report. Tuttle Report at 46-53.

<sup>32</sup> *In re Neurontin Mktg. & Sales Practices Litig.*, 04-cv-10739-PBS, 2011 WL 3852254 (D. Mass. Aug. 21, 2011), *aff'd*, 712 F.3d 21 (1st Cir. 2013).

hubris to opine on causation and criticize the opinions and methodology of the PSC's experts who actually reviewed the true breadth of relevant evidence. Despite her work and experience in assessing chemical exposures that have human health effects,<sup>33</sup> her report and more so her testimony reflects a litigation expert that is unprepared, unable, or unwilling to equip herself with a basic understanding of the toxicological, pathological, and mechanistic issues relevant to reliably and scientifically answer questions posed. Going beyond the reliability of her opinions and rebuttal opinions under *Daubert*, this failure overlaps with consideration of her fit as a potential expert witness because it is clear that she will be unable to help a jury understand complex scientific topics. To further illustrate these concerns, the below list of topics are basic scientific and methodological concepts discussed in Dr. Tuttle's report which she was [completely] unable to explain during her deposition:

- The methodologies for hazard and risk assessments, despite characterizing hazards and risks throughout her report and criticizing Dr. Plunkett's risk assessment of Talcum Powder Products;<sup>34</sup>

---

<sup>33</sup> J&J's Opposition to PSC's Toxicology Motion at 6.

<sup>34</sup> *Compare* Tuttle Dep. at 57:16-59:16 ("I'd have to go look at the regulations to see what is put forth in those regulations regarding the methodologies for hazard assessment – I can't just speak to it generally.") *and id.* at 59:18-61:4 ("vaguely" familiar with the NRC risk assessment methodology and insisting she would be unable to state whether this is one of the methodologies a toxicologist might use to perform a risk assessment) *with* Tuttle Report at 9-10, 58-59.

- The concept of reactive oxygen species, despite devoting sections of her report to carcinogenicity and genotoxicity and critiquing Dr. Zelikoff's opinions on inflammation and oxidative stress;<sup>35</sup>
- The concept of cytotoxicity, despite evaluating the cytotoxicity of a fragrance chemical in her report;<sup>36</sup>
- The concept of whether the ovaries or respiratory system can clear foreign particles, despite discussing the body's ability to clear asbestos fibers and other particles;<sup>37</sup>
- The concept of normal and intended use of talc, despite opining that levels of fragrance chemicals and additives through normal use of Talcum Powder Products would not cause adverse health effect;<sup>38</sup>
- The Physician Data Query (PDQ), despite defining the acronym and directly referencing the PDQ in her report to support her opinions;<sup>39</sup> and,

---

<sup>35</sup> Compare Tuttle Dep. at 324:4-12 (“So I don't know that I can really define that very clearly just, as I said, off the cuff. You know, reactive oxygen species, you know, I probably prefer to refer to a definition in front of me to make sure I'm speaking accurately regarding them”) with Tuttle Report at 12-13, 59-60.

<sup>36</sup> Compare Tuttle Dep. at 339:5-340:11 (“I'm not sure that I can define it very clearly and scientifically.”) & 344:2-14 with Tuttle Report at Appendix D (“Decanal”).

<sup>37</sup> Compare Tuttle Dep. at 138:2-139:24 (“I did not research ovaries and their ability to clear materials.”) and 140:1-141:3 (Q: “Does the respiratory system have the ability to clear foreign particles?... “A: Again, that's not something I address in my report”); with Tuttle Report at 33 (“fibers less than 5-10  $\mu$ m in length are often ... cleared through the normal defense mechanisms of the body, but that fibers longer than this are more difficult to clear”) (citing WHO) and Tuttle Dep. at 140:16-20 (“...the human body has -- has many defense mechanisms for removing materials from -- from its -- from the body”).

<sup>38</sup> Compare Tuttle Dep. at 344:15-345:17 with Tuttle Report at 67.

<sup>39</sup> Compare Tuttle Dep. at 198:4-199:4 (“I do not know what PDQ stands for”) and *id.* at 199:11-201:8 (“This isn't something that -- it's not a scientific article. I don't see any data included here”) with Tuttle Report at *vii*, 28 (“...in January of 2019 the

- The CTFA (Cosmetic, Toiletry, and Fragrance Association), despite defining the acronym and directly referencing CTFA work product to support her opinions.<sup>40</sup>

The discrepancy between the information contained in her expert report and her inability to communicate basic concepts through testimony may be explained in part by the plagiarism of large sections of the methodology section in her report.

J&J justifies Dr. Tuttle’s half-dozen pages of direct plagiarism and reframe it as “benign recycling” of “boilerplate concepts” from her work with a “colleague” on the “team” for an earlier project.<sup>41</sup> To suggest to this Court that plagiarism is benign recycling is nonsense. The PSC alleges that Dr. Tuttle, who joined CTEH in 2013,<sup>42</sup> plagiarized significant sections of her report from 2012 (prior to joining CTEH) and 2016 expert witness reports authored by a more senior toxicologist at her company.<sup>43</sup> Tellingly, J&J does not claim that she contributed to any of the passages she plagiarized.<sup>44</sup> Even if Dr. Tuttle had been candid about her verbatim

---

National Cancer Institute (NCI) updated its Physician Data Query (PDQ) on ovarian cancer and addressed perineal talc...”).

<sup>40</sup> Compare Tuttle Dep. at 261:23-262:7 with Tuttle Report at vii and 27.

<sup>41</sup> J&J’s Opposition to PSC’s Toxicology Motion at 38-40.

<sup>42</sup> CV of Kelly S. Tuttle, Ph.D.

<sup>43</sup> *Id.* and *cf.* PSC’s Toxicology Motion at Exhibit S (demonstrative comparison of Dr. Tuttle’s plagiarism from earlier CTEH reports).

<sup>44</sup> *Cf.* J&J’s Opposition to PSC’s Toxicology Motion at 38-40 (“...recycling the work product of a colleague with whom Dr. Tuttle has collaborated is simply *not* plagiarism) (original emphasis preserved). Dr. Tuttle also testified that the CTEH team that assisted her here, which did not include the author of the prior 2012 and

copying of prior reports, this would not have remedied her lack of knowledge, working understanding, and ability to explain those basic methodological concepts she plagiarized.

No doubt CTEH's "Team" approach explains Dr. Tuttle's inability to answer questions, her unfamiliarity with relevant topics, her inability to explain her methodology and ultimately her reliance on other experts for a more fulsome analysis of fundamental topics. Expert opinions are not a team sport. *Daubert* examines the individual expert's knowledge, skill, experience, training and education, not those of a team. At a trial, it would be Dr. Tuttle who would testify. So, what needs to be assessed is whether *she* is qualified and can offer reliable opinions. If she cannot, her opinions would be excluded. Here, Dr. Tuttle falls short of satisfying the requisite *Daubert* requirements.

This team reliance and need for plagiarism are crutches which cannot be substituted for a lack of qualifications, expertise, or preparedness to testify as an expert witness and should give the Court great pause when evaluating Dr. Tuttle's candor, reliability, and potential helpfulness to the finder of fact.

### **3. Dr. Tuttle's Opinion On Migration Is Unsupported And Unreliable**

---

2016 reports, did not contribute substantively to her report. Tuttle Dep. at 96:17-97:19 (team provided help with formatting, proofreading for typos, and punctuation).

Dr. Tuttle's failure to demonstrate requisite knowledge extends beyond the weaknesses in her methodologies. One of the primary themes Dr. Tuttle sought to advance during her deposition was the biologic plausibility of Talcum Powder Products migration to the ovaries. As the PSC previously detailed, Dr. Tuttle reiterated her opinion that there is "no scientific evidence" for migration approximately 30 times throughout her deposition, sometimes repeating it in response to completely unrelated topics.<sup>45</sup>

The PSC sought to test her opinions during her depositions, yet when questioned, she deferred repeatedly to other experts on many, if not most, of the fundamental science topics, including migration, defense mechanisms, ovarian tissue, biological plausibility, statistical analysis and inflammation.

Despite Dr. Tuttle's seeming confidence in her opinion about migration, and willingness to volunteer it *ad nauseum* during her deposition, she was repeatedly unable to support or even explain the basis for this opinion when examined further on the subject:

---

<sup>45</sup> PSC's Toxicology Motion at n. 131; Tuttle Dep. at 117:19-119:23 (touching on methodology and weight of the evidence, when asked "...as you gather the available literature, the body of scientific evidence, do you at some point in this process weigh the evidence to see what it tells you?," Dr. Tuttle volunteered "[w]ell, again, we're speaking in generalities...In the case of plausibility, as I said, the scientific evidence doesn't support the migration theory that perineal application can migrate to the ovaries").

- **On her theory that gravity affects migration:** “Well, as I said, I referred to it very generally in this sentence as part of an overall context regarding the other points that I used to address the migration theory. I know that there are others involved in this litigation that get into this in more detail than I do, so I would have to refer to them.”<sup>46</sup>
- **On her theory that gravity affects migration:** “Well, again, gravity is a scientific concept ...” “...so I included it here as one of several different things, and as I said, I think there are others who get into the nuances of migration theory much more in depth than I do.”<sup>47</sup>
- **Asked specifically which other experts address migration:** “Yes, I believe there are other experts involved that get more into the science of the migration theory and discuss those nuances and stuff in more detail than I do.”<sup>48</sup>
- **Asked whether she was comfortable discussing migration in the bounds of her expertise:** “I’m not a gynecologist, so as I said, there are others involved that get into this in more detail than I do, and I would have to refer to their work and the data that they use in what they provide, but ultimately, I would look at the scientific literature and generate my own conclusions.”<sup>49</sup>
- **Asked if she could share her perspective on the evidence of migration:** “I am aware that there are others involved in this litigation that, you know, focus on the migration theory much more specifically than I do and get into more detail.”
- **On her theory that downward flow of bodily fluids affects migration:** “I don’t believe I cite anything in that particular sentence. You know, I -- again, I didn’t get into great detail regarding the downward flow of bodily fluids, the female reproductive tract

---

<sup>46</sup> Tuttle Dep. at 127:8-14.

<sup>47</sup> *Id.* at 128:14-24.

<sup>48</sup> *Id.* at 129:12-16.

<sup>49</sup> *Id.* at 131:9-14.



and the fluids generated there. They have their own defense mechanisms against the introduction of foreign bodies and things like that. Again, I think that others in the -- involved in this litigation get into much more detail regarding that than I do.”<sup>50</sup>

- **As it relates to the destination of migrating talc, whether talc has been found in ovarian tissue:** “Well, again, in this particular report and in this -- because I did not do an assessment regarding just the presence of talc in the ovarian tissue. We can refer to my report where I discuss it in more detail regarding those things. I think others involved in this litigation get more in detail into that. I merely looked at it through the lens of the Hill criteria as far as the migration theory that perineal application can migrate to the ovaries.”<sup>51</sup>
- **As it relates to the destination of migrating talc, whether scientific literature shows evidence of talc in ovarian tissue:** “Again, I looked at the scientific evidence to see whether there have been any scientific evidence to support that talcum powder applied externally to the perineum can enter the vagina and transport through the female reproductive tract to the ovaries. I think that there are others involved in this litigation that get more into some of the questions you're asking, and so I would probably -- have to refer to their work and then again look at what they cite to do that type of assessment”<sup>52</sup>
- **Asked whether presence of talc in ovarian tissue is relevant to an analysis of migration:** “And as I've said previously, you know, there are others that get into the biological plausibility, the migration theory in more detail than I do. But in the context of my report and in the context of the body of science, we're specifically looking at that relationship between perineal application and ovarian cancer.”<sup>53</sup>

---

<sup>50</sup> *Id.* at 137:10-20.

<sup>51</sup> *Id.* at 211:3-14.

<sup>52</sup> *Id.* at 215:8-20.

<sup>53</sup> *Id.* at 245:6-13.

Dr. Tuttle's responses set forth above, provided when probed deeper about her migration opinion, clearly demonstrate that her opinion is pure *ipse dixit* and espoused with the hope that some other expert(s) would be able to provide the substance and authority to support it. The Court should exclude Dr. Tuttle's conclusory opinion that there is no evidence of migration and her associated rebuttal critiques of the PSC's experts on this subject.<sup>54</sup>

#### **4. Dr. Tuttle's Opinions On Inflammation And Carcinogenicity Lack Substance And Are Unreliable**

As with her unsupported migration opinion, Dr. Tuttle similarly espouses conclusory mechanistic opinions related to inflammation and carcinogenesis. As illustrated below, when probed deeper on the subjects, she repeatedly deferred to others and admitted she had not "brushed up" on the evidence regarding her opinions:

- "I believe there are others who get more into the mechanisms and pathways regarding inflammation than I do."<sup>55</sup>
- "Well, as I said, I didn't do an extensive review regarding the genetic mechanisms of inflammation, and again, inflammation is not the same as the initiation of cancer. And so, you know, I did not do a detailed review regarding the inflammatory process. We talked -- we quoted a few sentences from the paragraph that I have on page

---

<sup>54</sup> Had Dr. Tuttle actually endeavored to research the scientific literature and evidence of migration, she would see that it is a well-supported biologically plausible mechanism by which talcum powder can cause ovarian cancer. *See generally* PSC's Opposition to J&J's Biologic Plausibility Motion.

<sup>55</sup> Tuttle Dep. at 319:18-20.

27 where I look briefly at some of the studies that look at talc inflammation and ovarian cancer, but I have not done a detailed assessment of the inflammatory process or the genetic mechanism; therefore, I think there are others that do that.”<sup>56</sup>

- “I am aware generally that there are a very few number of cancers for which [inflammation] may be involved in the initiation process. I think that there's somebody else, another expert, that discusses that specifically.”<sup>57</sup>
- “I have not, I think I said earlier, brushed up on my understanding of the mechanistic toxicology or the mechanisms revolving inflammation in regards to my report or the assessment of talcum powder and ovarian cancer.”<sup>58</sup>
- “So again, you know, my opinions in my report are stated, and I briefly touch upon inflammation. That being said, my -- the scientific evidence does not support a causal association between talc and ovarian cancer. In regards to a plausible mechanism, we already discussed migration in depth. I don't, I believe, get into migration or, as I said, the mechanistics [sic] of inflammation in great detail in my report. I look at the scientific literature very generally. There are others that get more in depth as far as mechanisms than I do.”<sup>59</sup>

The finder-of-fact will be disserved if the Court's imprimatur of experience and reliability are lent to Dr. Tuttle's opinions and specific critiques of the PSC's experts' opinions on these subjects. For this reason, the Court should exclude Dr. Tuttle.

---

<sup>56</sup> *Id.* at 334:14-335:4.

<sup>57</sup> *Id.* at 336:5-10.

<sup>58</sup> *Id.* at 330:8-13.

<sup>59</sup> *Id.* at 337:9-22.

**C. THE EXPERT OPINIONS OF NADIA H. MOORE SHOULD BE EXCLUDED BECAUSE SHE LACKS ANY EXPERIENCE IN CANCER AND CELL BIOLOGY RESEARCH QUALIFYING HER TO CRITICIZE THE PSC'S EXPERTS AND BECAUSE THE METHODOLOGY SHE EMPLOYED IN REACHING HER OPINIONS ARE UNRELIABLE**

Dr. Moore is a toxicologist and industrial hygienist. J&J offers her opinions for two purposes: to criticize the opinions of the PSC's experts and to opine that there is insufficient evidence of a causal association between Talcum Powder Products and ovarian cancer. While it is acknowledged that rebuttal expert witness testimony is generally admissible, the PSC fairly challenges the admissibility of Dr. Moore's criticisms because she lacks the necessary experience and expertise in cancer and cell biology research to level reliable criticism of Dr. Saed. The PSC further challenges the admissibility of Dr. Moore's testimony regarding evidence of causation, because she systematically cherry-picked studies and research in reaching her conclusions and failed to consider the vast range of evidence available linking Talcum Powder Products use to ovarian cancer.

**1. Dr. Moore Lacks The Necessary Experience And Training To Criticize Dr. Saed's Cancer And Cell Biology Research**

In defending Dr. Moore's critique of Dr. Saed, J&J admits that Dr. Moore lacks necessary cell biology and cancer research experience.<sup>60</sup> In an effort to recast

---

<sup>60</sup> J&J's Opposition to PSC's Toxicology Motion at 55.

Dr. Moore's criticism, J&J claims it is not a criticism that relates to cancer biology, but is one that limited only to "fundamental principles of laboratory experiments."<sup>61</sup> J&J describes Dr. Moore's experience and qualifications to opine on this topic as something based and grounded in her "extensive experience as a scientist."<sup>62</sup> Dr. Moore describes her experience to rebut the PSC's experts as "a training that you go through as a graduate student on how to critique work and how to do methods correctly,"<sup>63</sup> and explained that "understanding methods and critically reviewing articles is just something that every graduate student is taught how to do."<sup>64</sup>

A cursory review of the relevant criticism of Dr. Saed in Dr. Moore's report<sup>65</sup> and J&J's response<sup>66</sup> demonstrate her opinions go far beyond the basics of Bunsen burner and pipettes handling and center directly on complex methods for conducting cancer and cell biology research: validation of assays (a review of the entire study methodology), plating and treatment of studied cells, and application of DMSO in cell control dishes. Unlike Dr. Moore, and as detailed at length in the PSC's response in opposition to J&J's motion to exclude Dr. Saed,<sup>67</sup> Dr. Saed is an eminently

---

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> Moore Dep. at 147:12-14.

<sup>64</sup> *Id.* at 148:1-3.

<sup>65</sup> Moore Report at 93-96.

<sup>66</sup> J&J's Opposition to PSC's Toxicology Motion at 55.

<sup>67</sup> *See* PSC's Opposition to Exclude Saed.

credentialed cancer biologist with over 30 years of cancer research experience. The PSC does not emphasize here that Dr. Saed is the better qualified of the two experts, but rather the *only* qualified of the two experts. For that reason, her criticism of Dr. Saed should be excluded.

**2. Dr. Moore's Opinions On The Mineralogy And Presence Of Particulates In Talcum Powder Products And Related Opinions On Talcum Powder Products Testing Should Be Excluded**

In response to the PSC's contention that Dr. Moore lacks the qualifications to opine on the presence of fibrous talc in Talcum Powder Products, J&J asserts this contention is moot because Dr. Moore did not opine on this topic in her report and only discussed the topic in responding to questioning at her deposition. The PSC's underlying motion to exclude covered more ground than J&J describes. The PSC sought to exclude Dr. Moore's testimony and opinions on the composition of Talcum Powder Products, minerology of talc, the presence of fibrous talc in Talcum Powder Products, the presence of asbestos in Talcum Powder Products, and the testing of Talcum Powder Products.<sup>68</sup> Given J&J's position on Dr. Moore's opinions regarding the presence of fibrous talc and the failure to object on the other topics, Dr. Moore's

---

<sup>68</sup> PSC's Toxicology Motion at 48-49 ("As Dr. Moore acknowledged, the portions of her report that pertain to composition (including the presence of asbestos and fibrous talc) or testing of talcum powder products lie outside the scope of her expertise and, therefore, any opinions in her report that purport to comment on those topics should be excluded.").

opinions should be excluded on the full range of topics requested for exclusion in this section of the PSC's motion.

### **3. Dr. Moore's Cherry-Picked Opinion On Causal Association Should Be Excluded**

Lastly, J&J justifies Dr. Moore's cherry-picking of favorable studies to reach her ultimate opinion on causation by inaccurately describing this flaw in methodology as being limited to two studies which, as J&J represents, are unhelpful to the PSC's position (Shukla *et al.* 2009) or would be "absurd" to lend any scientific weight to (Health Canada). Contrary to J&J's contention, these are merely examples of Dr. Moore's widespread dismissal and non-inclusion of many other relevant pieces of evidence supporting causation.

The Health Canada assessment was specifically addressed in the PSC's Toxicology Motion as an example of Dr. Moore's cherry-picking because it is one of the most recent governmental reviews of causal evidence and it cited a wealth of up-to-date literature in support. This recent publication has been a seemingly forbidden source for J&J's experts, which J&J has endeavored to mischaracterize as a rough draft of unreliable and untrustworthy foreign origin to which it would be "absurd" to lend scientific weight.<sup>69</sup> Despite this, Dr. Moore admitted during her

---

<sup>69</sup> J&J's Opposition to PSC's Toxicology Motion at 19, 58. Rather than address Defendants' crude mischaracterization of the Health Canada publication and assent to Defendants' bating on the topic as an "obsessive focus," *id.* at 19, Plaintiffs refer the Court back to its accurate and fulsome discussion of this highly relevant

deposition that she had read Health Canada while working on her report; however, she both failed to reference it in her report or disclose it in her list of materials considered.<sup>70</sup> Beyond Dr. Moore's failure to list Health Canada, Dr. Moore also ignored and failed to consider many of the sources cited by Health Canada.<sup>71</sup> This is

---

publication in its opposition memorandum on general causation. *See e.g., Plaintiffs' Steering Committee's Omnibus Memorandum of Law in Response and Opposition to Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Plaintiffs' General Causation Opinions*, (ECF No. 9914) (corrected version) at 84-91.

<sup>70</sup> Moore Dep. at 166:10-168:13.

<sup>71</sup> Dr. Moore ignored nearly a dozen studies cited by Health Canada in their up-to-date review of Talcum Powder Products and ovarian cancer. *See, e.g.,* Narod S (2016). Talc and ovarian cancer. *Gynecologic Oncology* 141(3):410-12; L.-m. Chen, J.S. Berek, Epithelial carcinoma of the ovary, fallopian tube, and peritoneum: Epidemiology and risk factors, *UpToDate*, 2014; Lo-Ciganic, W. H., J. C. Zgibor, C. H. Bunker, K. B. Moysich, R. P. Edwards and R. B. Ness (2012). Aspirin, nonaspirin nonsteroidal anti-inflammatory drugs, or acetaminophen and risk of ovarian cancer. *Epidemiology* 23(2): 311-319; A.J. Ghio, J.M. Soukup, L.A. Dailey, J.H. Richards, J.L. Turi, E.N. Pavlisko, V.L. Roggli, Disruption of iron homeostasis in mesothelial cells after talc pleurodesis, *Am J Respir Cell Mol Biol* 46(1) (2012) 80-86; Shukla A, M MacPherson, J Hillegass, M Ramos-Nino, V Alexeeva, P Vacek, J Bond, H Pass, C Steele, B Mossman (2009). Alterations in gene expression in human mesothelial cells correlated with mineral pathogenicity, *American Journal of Respiratory Cell and Molecular Biology*, 41:114-123; Ness, R. B. and C. Cottreau (1999). Possible role of ovarian epithelial inflammation in ovarian cancer. *Journal of the National Cancer Institute* 91(17): 1459-1467; M.M. van den Heuvel, H.J. Smit, S.B. Barbierato, C.E. Havenith, R.H. Beelen, P.E. Postmus, Talc-induced inflammation in the pleural cavity, *Eur Respir.J* 12(6) (1998) 1419-1423; N. Nasreen, D.L. Hartman, K.A. Mohammed, V.B. Antony, Talc-induced expression of C-C and C-X-C chemokines and intercellular adhesion molecule-1 in mesothelial cells, *Am J Respir Crit Care Med* 158(3) (1998) 971-8; J.C. Wagner, G. Berry, T.J. Cooke, R.J. Hill, F.D. Pooley, J.W. Skidmore, Animal experiments with talc, in: W.H. Walton, B. McGovern (Eds.), *Inhaled Particles IV*, Part 2, Pergamon Press, 714 Oxford, UK, 1977, pp. 647-654; Rohl A, A. Langer, J.



of particular importance as the Health Canada study reviewed decades of science pertinent to the issue of causation.

Shukla was specifically cited as an example of Dr. Moore's cherry-picking because it was conducted in-part by one of J&J's own experts (Dr. Mossman) and demonstrated genotoxicity of industrial non-fibrous talc and asbestos in cell cultures – a subject highly relevant to an evaluation of a causal link between Talcum Powder Products and ovarian cancer.<sup>72</sup>

In assessing the dose of asbestos-contamination of Talcum Powder Products, Dr. Moore failed to consider genital migration of Talcum Powder Products and instead limited her calculations of asbestos exposure to inhalation pathways only.<sup>73</sup> Moreover, Dr. Moore failed to consider the chronic exposure of regular use over an extended period of time. This further exemplifies Dr. Moore's incomplete analysis of relevant evidence.

---

Selikoff, A. Tordini, R. Klimentidis (1976). Consumer talcums and powders: mineral and chemical characterization. *Journal of Toxicology and Environmental Health* 2(2):255-84.

<sup>72</sup> J&J's further attempts to justify Dr. Moore's failure to include Shukla 2009 by claiming the study does not support causation because it resulted in identical effects of gene expression by talc and inert particles in peritoneal mesothelioma cells. This is not correct. Dr. Mossman's expert report states that the inert particles did not induce significant changes in gene expression in cell culture in contrast to talc and asbestos. Mossman Rep. at 25. Furthermore, the study itself explains that "[f]ine TiO<sub>2</sub> or glass beads caused no changes in gene expression." Shukla *et al.* 2009 at 114.

<sup>73</sup> Moore Dep. at 262:3-263:4.

Leaving out these key lines of evidence and failing to consider the totality of the evidence available on Talcum Powder Products and ovarian cancer exemplifies Dr. Moore's impermissible cherry-picking and sufficiently warrants exclusion of her opinions on causal association.

For the foregoing reasons, the PSC requests the opinions of toxicology expert H. Nadia Moore, Ph.D. be excluded.

### **III. CONCLUSION**

For the foregoing reasons, the PSC requests that the opinions of J&J's toxicology experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D., and H. Nadia Moore, Ph.D. be excluded.

Respectfully submitted,

/s/ Michelle A. Parfitt

Michelle A. Parfitt  
ASHCRAFT & GEREL, LLP  
1825 K Street, NW, Suite 700  
Washington, DC 20006  
Tel: 202-783-6400  
Fax: 202-416-6392  
[mparfitt@ashcraftlaw.com](mailto:mparfitt@ashcraftlaw.com)

/s/ P. Leigh O'Dell

P. Leigh O'Dell  
BEASLEY, ALLEN, CROW, METHVIN,  
PORTIS & MILES, P.C.  
218 Commerce Street  
Montgomery, AL 36104  
Tel: 334-269-2343  
Fax: 334-954-7555

[Leigh.odell@beasleyallen.com](mailto:Leigh.odell@beasleyallen.com)

***Plaintiffs' Co-Lead Counsel***

/s/ Christopher M. Placitella

Christopher M. Placitella

COHEN, PLACITELLA & ROTH, P.C.

127 Maple Avenue

Red Bank, NJ 07701

Tel: 732-747-9003

Fax: 732-747-9004

[cplacitella@cprlaw.com](mailto:cplacitella@cprlaw.com)

***Plaintiffs' Liaison Counsel***

**PLAINTIFFS' EXECUTIVE COMMITTEE:**

Warren T. Burns

BURNS CHAREST LLP

500 North Akard Street, Suite 2810

Dallas, TX 75201

Tel: 469-904-4551

Fax: 469-444-5002

[wburns@burnscharest.com](mailto:wburns@burnscharest.com)

Richard Golomb

GOLOMB & HONIK, P.C.

1515 Market Street, Suite 1100

Philadelphia, PA 19102

Tel: 215-985-9177

[rgolomb@golombhonik.com](mailto:rgolomb@golombhonik.com)

Richard H. Meadow

THE LANIER LAW FIRM PC

6810 FM 1960 West

Houston, TX 77069

Tel: 713-659-5200

Fax: 713-659-2204

[richard.meadow@lanierlawfirm.com](mailto:richard.meadow@lanierlawfirm.com)

Hunter J. Shkolnik

NAPOLI SHKOLNIK PLLC

360 Lexington Avenue, 11th Floor

New York, NY 10017

Tel: 212-397-1000

[hunter@napolilaw.com](mailto:hunter@napolilaw.com)

**PLAINTIFFS' STEERING COMMITTEE:**

Laurence S. Berman

LEVIN, SEDRAN & BERMAN LLP

510 Walnut Street, Suite 500

Philadelphia, PA 19106

Tel: 215-592-1500

Fax: 215-592-4663

[lberman@lfsblaw.com](mailto:lberman@lfsblaw.com)

Timothy G. Blood

BLOOD, HURST & O'REARDON,  
LLP

701 B Street, Suite 1700

San Diego, CA 92101

Tel: 619-338-1100

Fax: 619-338-1101

Sindhu S. Daniel  
BARON & BUDD, P.C.  
3102 Oak Lawn Avenue, #1100  
Dallas, TX 75219  
Tel: 214-521-3605  
Fax: 214-520-1181  
[sdaniel@baronbudd.com](mailto:sdaniel@baronbudd.com)

Kristie M. Hightower  
LUNDY, LUNDY, SOILEAU & SOUTH,  
LLP  
501 Broad Street  
Lake Charles, LA 70601  
Tel: 337-439-0707  
Fax: 337-439-1029  
[khightower@lundylawllp.com](mailto:khightower@lundylawllp.com)

Victoria Maniatis  
SANDERS PHILLIPS GROSSMAN, LLC  
100 Garden City Plaza, Suite 500  
Garden City, NJ 11530  
Tel: 516-640-3913  
Fax: 516-741-0128  
[vmaniatis@thesandersfirm.com](mailto:vmaniatis@thesandersfirm.com)

Eric H. Weinberg  
THE WEINBERG LAW FIRM  
149 Livingston Avenue  
New Brunswick, NJ 08901  
Tel: 732-246-7080  
Fax: 732-246-1981  
[ehw@erichweinberg.com](mailto:ehw@erichweinberg.com)

Christopher V. Tisi  
LEVIN PAPANTONIO  
316 South Baylen St.  
Pensacola, FL 32502

[tblood@bholaw.com](mailto:tblood@bholaw.com)

Jeff S. Gibson  
WAGNER REESE, LLP  
11939 N. Meridian St.  
Carmel, IN 46032  
Tel: (317) 569-0000  
Fax: (317) 569-8088  
[jgibson@wagnerreese.com](mailto:jgibson@wagnerreese.com)

Daniel R. Lapinski  
MOTLEY RICE LLC  
210 Lake Drive East, Suite 101  
Cherry Hill, NJ 08002  
Tel: 856-667-0500  
Fax: 856-667-5133  
[dlapinski@motleyrice.com](mailto:dlapinski@motleyrice.com)

Carmen S. Scott  
MOTLEY RICE LLC  
28 Bridgeside Boulevard  
Mount Pleasant, SC 29464  
Tel: 843-216-9162  
Fax: 843-216-9450  
[cscott@motleyrice.com](mailto:cscott@motleyrice.com)

Richard L. Root  
MORRIS BART, LLC  
Pan America Life Center  
601 Poydras St., 24<sup>th</sup> Fl.  
New Orleans, LA 70130  
Tel. 504-525-8000  
Fax: 504-599-3392  
[rroot@morrisbart.com](mailto:rroot@morrisbart.com)

(850) 435-7000  
[ctisi@levinlaw.com](mailto:ctisi@levinlaw.com)